European Monitoring Centre
for Drugs and Drug Addiction

Medical use of cannabis – a review of the regulatory frameworks and challenges

Lisbon Addictions 2019

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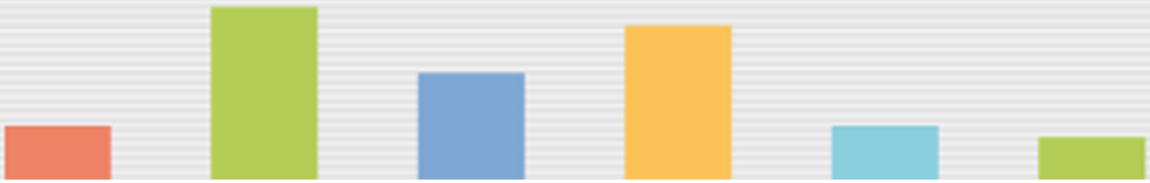
Thursday, 24 October 2019



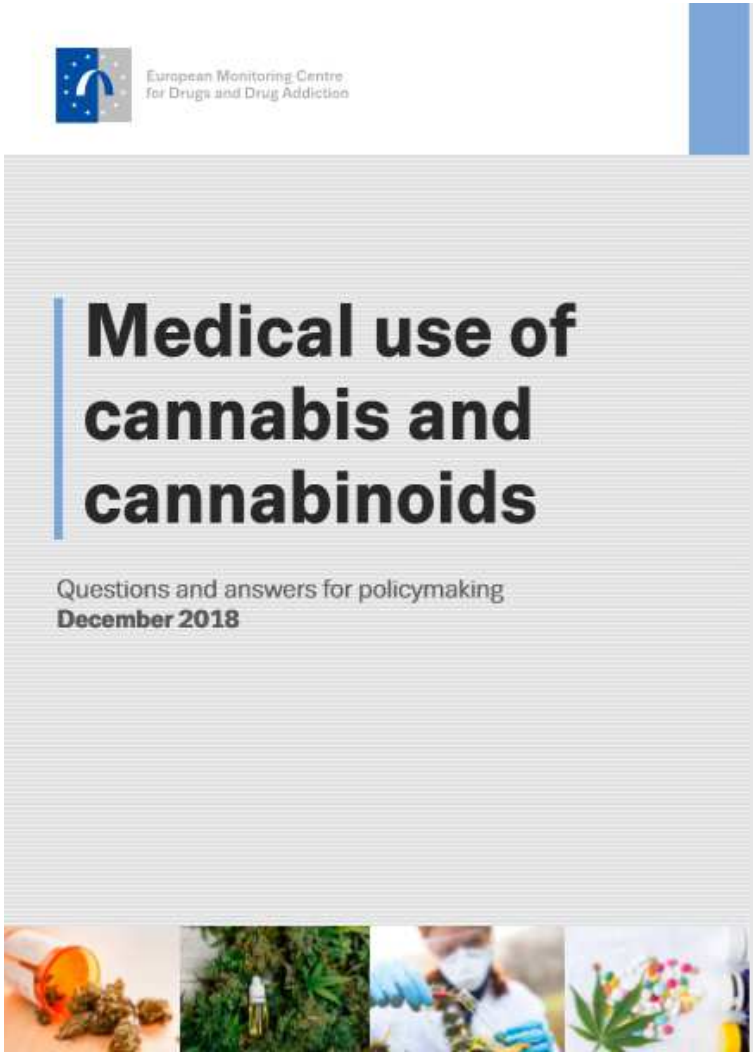
Medical use of cannabis

EMCDDA project group:

Liesbeth Vandam, Brendan Hughes, Nicola Singleton, Jane Mounteney, Paul Griffiths

Prepared by Wayne Hall

+ Hall, 2018 – Background paper - *a summary of reviews of evidence on the efficacy and safety of medical uses of cannabis and cannabinoids.*



Raise hands if…

- **Do you know at least one clinical indication that cannabis can be used for?**
- **Can you obtain a prescription for medical use of cannabis or cannabinoids in your country?**
- **Your country allows smoking of ‘medical cannabis’?**

A broad typology

Cannabis and cannabinoids used for medical purposes — a broad typology

	Examples of medicinal products and their active ingredients			
	Cesamet and Canemes	Marinol and Syndros	Sativex	Epidiolex
Medicinal products with marketing authorisation	Containing nabilone	Containing dronabinol	Containing nabiximols	Containing cannabidiol
	Synthetic cannabinoid similar to THC	Synthetic THC	Plant-based; approx. equal quantities CBD/THC	Plant-based CBD

Cannabis preparations	Raw cannabis	Magistral preparations	Standardised cannabis preparations
	Variable in THC/CBD composition		

The current evidence (1 of 2)

Limitations: evidence base is evolving rapidly, but currently quite limited and fragmented; in addition, often different cannabis products and preparations have been used.

Diseases / Symptoms	Products tested	Strength of evidence	Limitations
Chronic non-cancer pain, including neuropathic pain	Cannabis and cannabinoids	Moderate	Small (but statistically significant) effect compared with placebo.
Muscle spasm in patients with multiple sclerosis	Nabiximols	Moderate	Patients report reductions, but more limited impact on clinician ratings.
Intractable childhood epilepsy	CBD	Moderate	Evidence for use in adjunctive therapy in people with Dravet or Lennox-Gastaut syndrome. More studies are needed to look at dosage, interactions and use in people with other forms of epilepsy.

The current evidence (2 of 2)

Diseases / Symptoms	Products tested	Strength of evidence	Limitations
Palliative care for cancer	Cannabinoids	Insufficient	Larger, better-designed trials are needed.
Other medical uses, such as sleep disorders, anxiety disorders, depression, degenerative neurological disorders, and inflammatory bowel disease	Cannabis or cannabinoids	Insufficient	Some evidence for short-term effects in some conditions (e.g. sleep disorders) but larger, better-designed trials are needed, with longer follow-up.
Nausea and vomiting associated with cancer chemotherapy	Cannabinoids	Weak	Few studies testing against newer, more effective anti-emetics. Newer chemotherapy regimens produce less nausea. Little evidence available about use in other types of nausea.
Appetite stimulant in patients with AIDS-related wasting	Dronabinol / THC	Weak	Fewer AIDS-related cases available to treat now. Little evidence available about use to stimulate appetite in people with other conditions

The current evidence

- Cannabinoids relieve the *symptoms* of some illnesses
- Used as *adjunctive treatments*, i.e. added to other medical treatments rather than used on their own
- They are also typically used only after a patient has failed to respond to recommended treatments for these conditions
- Need for additional research and clinical studies (including larger trials, studies looking at dosage and interactions, and studies with longer follow-up)
- *Harms* are similar to those of other commonly used medicines and serious adverse events are rare

Regulatory frameworks

- **International Drug Control Treaties:**

- ‘Cannabis’ included in (Schedule I and) Schedule IV of UN Single Convention 1961 – ‘serious risk of abuse’ + ‘no medical value’
- Recent development: WHO-ECDD recommendations, including:

  -Pure CBD should not to be placed under international drug control

  -Remove cannabis from schedule IV

- **Different routes of medicines authorisation in Europe**
  - Centralised / decentralised / mutual recognition procedures.
  - Epidyolex – first EU-wide marketing authorisation for cannabinoid-containing medicine (active substance: cannabidiol)

Regulatory frameworks

- **EU - regulatory approaches exist for making cannabis and cannabinoids available to patients without formal marketing authorisation**
  - Compassionate accesss programmes – a specialised prescriber who has a specific licence to prescribe non-authorised cannabis preparations
  - Expanded access programmes – country specific regulatory tools

- **De novo stand alone medical cannabis programmes**
  - For example: regulatory requirements for medicines have been avoided by passing citizen initiated referenda that allow patients to smoke cannabis and use other cannabis products for very broadly defined medical reasons

The medical use of cannabis and cannabinoids in the EU – medicinal products

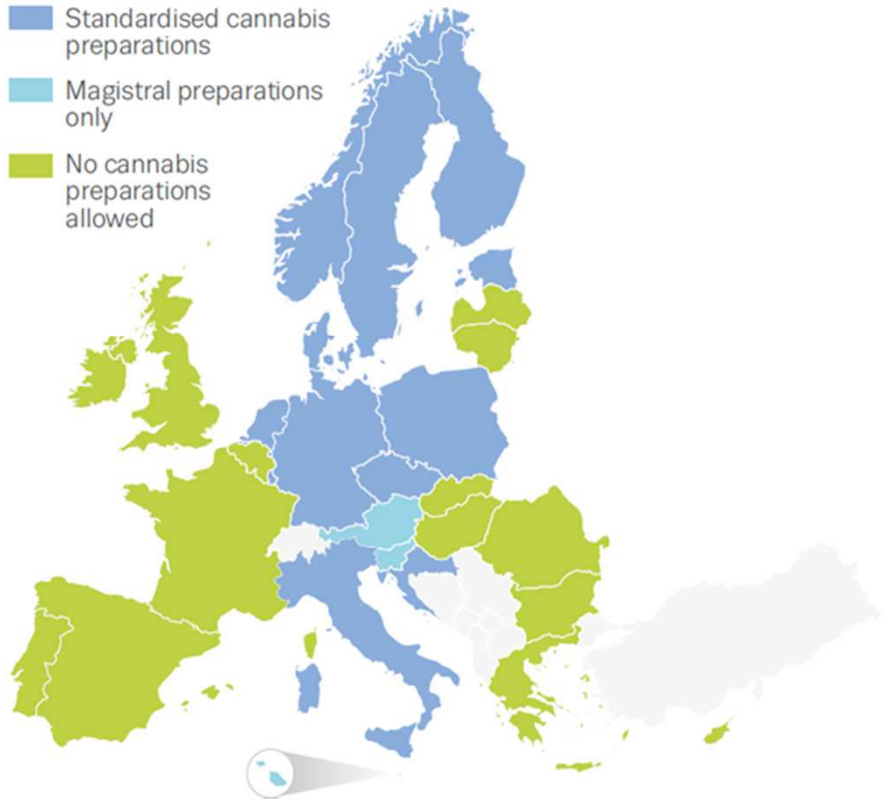
- Nabiximols (Sativex) – available in the majority of EU countries (Muscle spasm in patients with multiple sclerosis)
- Medicinal products containing dronabinol and nabilone are less widespread (1/3 of countries)
- Epidyolex – EU-wide marketing authorisation since September 2019
- In some of these countries, national health insurance systems will reimburse the costs under certain conditions

The medical use of cannabis and cannabinoids in the EU – cannabis preparations

- Increasing number of countries allow cannabis preparations for medical use
- Very dynamic area, policies and practice are evolving rapidly
- A variety of approaches at national level
- Standardised preparations (such as Bedrocan®) versus magistral preparations,
- Different routes of administration allowed
- Different indications and applications

Situation December 2018

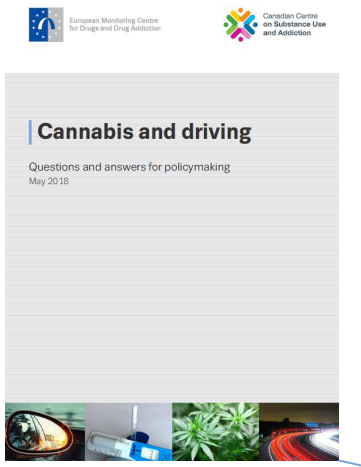
Availability of cannabis preparations for medical use in the European Union and Norway

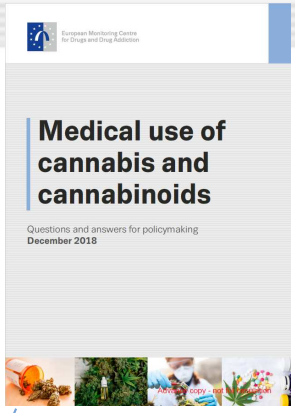


Regulatory challenges

- ✓ What type of products will be allowed? Medicinal products versus cannabis preparations?
- ✓ Raw cannabis, magistral preparations, other preparations?
- ✓ What routes of administration are allowed?
- ✓ For which medical conditions?
- ✓ Who is authorised to make prescriptions?
- ✓ How to organise training and guidelines for prescribers?
- ✓ How much of the cost will be met by patients?
- ✓ How should monitoring of patients outcomes be carried out?
- ✓ What type of quality standards should be applied?
- ✓ How should manufacturing be organised?

EMCDDA reports





Reports from the EMCDDA – a focus on cannabis

Low-THC Cannabis products (2019)

Monitoring and evaluating changes in cannabis policies in the Americas – Insights for Europe (2019)

Ongoing:

DRUG POLICY NEWS
Cannabis

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